traverses this objection, the term "wall" has been changed to the term "surface". Such a surface may correspond, for example, to annular surface 14 as illustrated in FIG. 2 and described in the specification. As such, Applicant asserts that the objection has been obviated.

The Examiner has objected to the specification and claim 21 in particular because it is "unclear" to the Examiner how the "valve/disk of claim 21 prevents the back-flow of fluid into the container since it appears that Applicant teaches a device which prevents back-flow in the specification." Applicant respectfully asserts that this objection is a) improper; b) unsupported by any legal requirement of patent practice; c) factually incorrect; and d) inconsistent with the claim language of claim 21.

Specifically, claim 21 depends from claim 17 and reads in part: "wherein the valve contains a plurality of openings." Neither claim 17 nor claim 21 require, either explicitly or implicitly, that "back-flow" be prevented. Applicant is unsure why the Examiner is trying to read such a limitation into claim 21 and more importantly why the Examiner has focused on this issue with respect to the specification. Applicant can only assume that the Examiner has not fully appreciated the teachings of the specification and the functionality of the present invention. Specifically, back-flow prevention (which may in fact be accomplished by the device of claim 21) is not a requirement of the claims. Rather, the present invention provides a valve in such a device that is located between a fluid supply (e.g. an ampoule) and a fluid dispensing point (e.g., a needle). The valve will only open when a particular pressure is achieved on the fluid supply side. That pressure being greater than the dead weight of the fluid so that the weight of the fluid alone will not open the valve. Back-flow is exactly the opposite concept wherein fluid flow is prevented in a direction from the needle (or similar point) back into the fluid supply.

Applicant has assumed that the Examiner does not understand how a valve having the claimed "plurality of openings" will function according to the teachings of the present invention. The following description is meant to illustrate the operation of one example of the present invention in order to illustrate the basic concepts to the Examiner and is not meant to in any way limit or define the invention beyond the specification. With reference to FIG. 2, valve body 31 contains a plurality of openings 32. A portion of valve body 31 selectively abuts against sealing lips 15. Fluid flow normally occurs from left to right as illustrated. Thus, as the fluid pressure reaches a predetermined value, valve body 31 moves away sealing lips 15 and allows fluid flow

through the plurality of openings 32. While irrelevant to the claims, back-flow is prevented in this embodiment because fluid flow from right to left is prevented, as valve body 31 blocks sealing lips 15 and any pressure generated by back-flow serves to further seal valve body 31 against sealing lips 15.

Thus, claim 21 and the referenced portions of the specification are proper and consistent. The Examiner's objection is believed to be improper and Applicant respectfully requests that the objections be withdrawn.

With respect to the claim rejection under 35 U.S.C. 112, Applicant respectfully asserts that the rejection has been obviated, as addressed above with respect to the objection to the drawings.

Claims 1, 5 and 16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Michel et al. ("Michel"). Applicant respectfully traverses this rejection. The Examiner states that Michel teaches "a valve . . . wherein fluid flow is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds [sic] a pressure on the inlet end caused by the dead weight of the fluid drug." Applicant respectfully requests the Examiner to point out specifically within the reference where such a statement has support. Applicant respectfully asserts that Michel teaches nothing of the sort. As such, the reference cannot anticipate the claim.

Rather, the Examiner appears to be relying on the mere conclusion that addressing the issues related to the dead weight of the fluid are "a phenomenon common to all syringe type devices with a piston." If the Examiner maintains such a conclusory statement, he is respectfully requested to provide a reference that teaches the concept. Michel does not address the issue at all, let alone anticipate the presently claimed invention. Michel does not actually teach a specific valve structure whatsoever, but merely indicates that a valve could be utilized. However, the purpose of such valve, as indicated at Col 6, lines 1-6 and Col 5, lines 1-6 is to provide a bypass passageway that can be selectively externally and manually opened and closed to allow the introduction of additional fluids. The graphs of FIGS. 2a-2e indicate the various delivery options. That of FIG. 2D indicates a continuous administration in combination with the sporadic additional introduction of a bolus 44. That is what the valve would be provided for. It would be manually openened or closed and has no relation to the fluid pressure contained within container

3. The only information to the contrary is the Examiner's conclusory statement. As Michel fails to teach each and every element of the at least claim 1, Applicant respectfully requests that the Examiner withdraw the rejections.

Claims 2 and 6-9 were rejected under 35 U.S.C. 103(b) as being unpatentable over Michel in view of Paradis. The Examiner asserts that Michel provides all of the limitations of the claims but fails to teach the specific valve structures claimed. Applicant respectfully traverses these rejections. As explained above, Michel fails to teach opening a valve when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug. Rather, Michel provides a valve that is manually opened and closed to allow the introduction of additional fluids and fails to address the issue of the dead weight of the fluid. Michel provides no teaching or motivation to add a valve to address such an issue and the only suggestion provided by the Examiner is Applicant's own claim language – thus clearly falling within the scope of impermissible hindsight.

Pardis fails to provide for the deficiencies noted above. Furthermore, the valve structure taught by Pardis is incompatible with the objective of Michel in that selective additional fluid flow cannot be controlled with the check valve taught by Pardis. That is, fluid flow in one direction is always allowed with the Pardis device. In addition, Pardis is only concerned with the prevention of back-flow – a feature erroneously read into the claims and focused on by the Examiner. Thus, Michel and Pardis alone or in combination fail to teach the presently claimed invention and the Examiner is respectfully requested to withdraw the rejection.

Claims 17-18, 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Boettger in view of Pardis. Applicant respectfully traverses these rejections. Again the Examiner seems to have confused a valve whose only purpose is the prevention of back-flow with the presently claimed valve that permits flow of the fluid drug through the valve from the outlet to the injection needle when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug. Furthermore, the Examiner again states that this reference also teaches that the "flow of fluid is permitted . . . when pressure is exerted . . . exceeds [sic] a pressure . . . caused by the dead weight of the fluid drug." Boettger teaches no such concept. Rather, Boettger teaches a valve that is opened upon assembly of the components and prevents back-flow. Col. 5, lines 50-62 and Col. 6, lines 15-19.

Boettger does not address or provide a mechanism to address the issue of the dead weight of the fluid. If the Examiner continues to maintain such a position, Applicant respectfully request that the Examiner point to specific language within the reference that supports that assertion.

The Examiner does not specify what he believes is lacking from Boettger and for what Paradis is relied on. Thus, Applicant asserts that Boettger is deficient, as explained above and Paradis does not provide what Boettger lacks. The Examiner does state that "it appears that claim 21 would allow for fluid to pass back into the container as addressed in the objections." This statement is factually incorrect but also completely irrelevant to the claimed subject matter. Applicant once again points out that the force exerted by the dead weight of the fluid is in a direction opposite to that of any potential back-flow. Furthermore, a device consistent with claim 21 is also quite capable of preventing backflow but such a requirement is not part of the claim.

Applicant respectfully asserts that all of the pending claims patentably define over the prior art. As such, the Examiner is respectfully requested to withdraw the rejections and pass this case to issue. Further, as the previously identified generic claims are in condition for allowance, the Examiner is also respectfully requested to allow the claims to species withdrawn from consideration.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP

Date: October 9, 2001

By: David E Bruhn

David E. Bruhn (Reg. No. 36,762)
DORSEY & WHITNEY LLP
Pillsbury Center South
220 South Sixth Street
Minneapolis, MN 55402
(612) 340-6317

MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

8. (Amended) The device according to claim 7, wherein the valve body is tensioned over the sealing lip in the direction of a [wall] surface of a fluid-proof housing accommodating the valve body, the wall being situated upstream on said sealing lip.